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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/528,963	03/21/2000	Gustavo C Rodriguez	31162	8022

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EXAMINER
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HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/528,963

Applicant(s)

RODRIGUEZ, GUSTAVO C

Examiner

Raymond J. Henley III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

**CLAIMS 1-5 ARE PRESENTED FOR EXAMINATION**

Applicant's Amendment filed July 21, 2003 has been received and entered into the application. Accordingly, claim 6 has been canceled and the specification at page 1, line 5 has been amended to include applicant's claim to priority based upon several U.S. Applications. Because the effective date of the present application now pre-dates the reference relied upon in the previous Office action dated April 24, 2003, i.e., WO 98/0771, the rejection based upon that reference is withdrawn.

Also, in light of the cancellation of claim 6, the rejection set forth under 35 U.S.C. 112, second paragraph in the previous Office action is withdrawn.

The Election Requirement set forth in the Office action dated June 15, 2001 is also withdrawn.

***Claim Rejection - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Because of the cumbersome nature of the wording employed in claim 1, which includes multiple dependent/independent clauses having to apparent relationship, and because it is not seen that a step is included in claim 1 whereby the objective of "formulating a composition" is achieved and because the present claim 1 can be reasonably interpreted as defining a method of preparing a formulation, rather than for determining the effectiveness of an agent for preventing

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epithelial ovarian cancer, claim 1, and its dependents, are not seen to clearly delineates the metes and bounds of the subject matter for which applicant seeks patent protection.

In order the expedite prosecution, applicant may wish to employ the following or similar language in place of that used in present claim 1 in order to overcome the present rejection:

“A method for determining the effectiveness of an agent for preventing epithelial ovarian cancer in a human female, based upon the ability of said agent to upregulate TGF- $\beta$  in ovarian epithelium, said method comprising the steps of

- (a) exposing said agent to ovarian epithelial cells;
  - (b) measuring the resulting expression of TGF- $\beta$  in the exposed ovarian epithelial cells;
- and
- (c.) determining the agent to be effective for the prevention of epithelial ovarian cancer in a human female when said measuring step indicates an upregulation of TGF- $\beta$  in said ovarian epithelial cells.”

The Examiner finds support for this claim at page 57 of the present specification, last paragraph through page 58, end of the first full paragraph.

In the dependent claims, applicant should ensure conformance with 35 U.S.C. 112, second paragraph with regard to antecedent basis, etc.


None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is 703-308-4652. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Raymond J. Henley III  
Primary Examiner  
Art Unit 1614

Dec. 5, 2003